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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,816	12/28/2000	Tatsuro Kawamura	43888-092	3440

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EXAMINER

COLE, MONIQUE T

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 01/16/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/749,816

Applicant(s)

KAWAMURA, TATSUROU

Examiner

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-15 and 17 is/are rejected.
- 7) ☒ Claim(s) 9-11 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

1. Claim 10 is objected to because of the following informalities: it is dependent upon itself. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no correlation step recited between the light intensities and the protein amount. Absent such a recitation, it is not clear how the concentration of the protein can be measured. It is suggested that the limitation of claim 5 be placed in claim 1, along with a further explanation of how the differential between transmitted light and scattered light is indicative of protein amount.
3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 should read as follows: The reagent for measuring a concentration of protein of claim 12, wherein said reagent contains a pH controlling agent to regulate the pH of the solution to the range of 1.5 to 5.8.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 5, 6, 7, 12, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,264,589 to Corey (herein referred to as "Corey '589").

Corey '589 teaches that a known method for the determination of the presence of protein consists of measuring turbidity following sample acidification. According to this known method, the turbidity of the sample is measured using a spectrophotometer following the addition of a protein-precipitating agent, generally an acidifying agent, to the sample. The calculated turbidity of the sample is compared to the spectrophotometric standard curves to determine the presence of protein in the sample. Common precipitating agents include sulfosalicylic acid, trichloroacetic acid and tannic acid. See col. 1, lines 45-55.

While Corey '589 does not explicitly teach measuring intensity before and after the addition of tannic acid, it is clear that this step has been performed in order to generate the

Art Unit: 1743

spectrophotometric standard curve used to calibrate protein amount. Further, with regard to claim 7, while Corey '589 does not disclose such a correction procedure, it would have been well within the skill of the art to recognize procedural problems that may lead to a skewed result and have some means to compare the result to that indicative of a problem.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,036,922 to Kawamura et al. (herein referred to as "Kawamura '922) in view of Corey '589.

Kawamura '922 teaches measuring the protein levels of a liquid sample on the basis of the intensity of the transmitted or scattered light. Further, measurement of the angle of rotation of the sample provides information on optically active substances present in the sample. If the angle of rotation of said sample is determined, then the sample components can be determined with high accuracy by measuring the degree of turbidity (col. 3, lines 1-7).

Kawamura '922 teaches the presently claimed invention substantially as claimed with the exception of the addition of an acid to the liquid sample.

Corey '589 teaches that a known method for the determination of the presence of protein consists of measuring turbidity following sample acidification. According to this known method, the turbidity of the sample is measured using a spectrophotometer following the addition of a protein-precipitating agent, generally an acidifying agent, to the sample. The calculated turbidity of the sample is compared to the spectrophotometric standard curves to determine the presence of protein in the sample. Common precipitating agents include sulfosalicylic acid, trichloroacetic acid and tannic acid. See col. 1, lines 45-55. Thus, given that it is generally recognized by those of ordinary skill in the art that the addition of acid facilitates the detection of

Art Unit: 1743

protein, it would have been obvious to one having ordinary skill in the art to modify Kawamura '922 by including the addition of acid, prior to the determination of protein concentration.

*Allowable Subject Matter*

Claims 2-4, 9-11, 13 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest regulating the pH of the solution to be detected to the recited pH range; the prior art does not teach or suggest the concentration range of the reagent in the amount claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole  
Examiner  
Art Unit 1743

Application/Control Number: 09/749,816

Page 6

Art Unit: 1743

MC *MC*  
January 13, 2003

*Jill Warden*  
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